UGANDA NATIONAL COUNCIL
FOR SCIENCE & TECHNOLOGY

THE REPUBLIC OF UGANDA

NATIONAL RESEARCH BIOBANKING GUIDELINES

JANUARY 2021

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Document Errors

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First Edition

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Foreword

Biobanks, collect, receive, store, process, and disseminate biological specimens and associated data as needed for research and technology. Biobanks play a crucial role in ensuring that quality bio specimens are available to foster scientific research and collaborations, health care and public health purposes. Biobanks currently exist in Uganda, with majority hosted in research institutions, public sector and academia. However, development and expansion of biobanks network capacity locally continues to face challenges since host institutions have to consider a series of ethical, legal and social issues; (informed consent, benefit sharing, confidentiality, ownership, commercialization and public engagement). Maintaining these biobanks and producing effective outcomes is challenging without a proper regulatory and governance framework. Researchers and public health specialists, continue to cite lack of access to high quality, well identified samples as a major hindrance to their work.

The National Research Biobanking Guidelines provide a framework for establishing, certification and operation of the biobanks in health care, agriculture; horticulture, veterinary, forensic, environment, aquatic sciences, wildlife and education. The benefits resulting from access to biospecimens and associated data of biobanks underscores the urgent need for these guidelines. It is our hope that these guidelines will ensure that Biobanks are established for custodianship of high quality, highly valuable biological materials and data, and maintain ethical standards, legal standards and ensure biosafety and biosecurity in collection, acquisition, processing, storage or inventory, disposal, use and distribution of biological materials with their associated data.

We commend the Technical Working Group for the biobanking guidelines and stakeholders that participated in the development of these guidelines. We pledge our support to enable their implementation nationally.

MARTIN PATRICK ONGOL (PhD)

For: Executive Secretary, Uganda National Council for Science and Technology

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List of Acronyms

CDC	U.S Centers for Disease Control and Prevention
CHS	College of Health Sciences
DMM	Department of Medical Microbiology
DNA	Deoxyribonucleic Acid
DTA	Data Transfer Agreement
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
IATA	International Air Transport Association
IBC	Institutional Bio-safety Committee
ICFs	Informed Consent Forms
ISBER	International Society for Biological and Environmental Repositories
IDI	Infectious Diseases Institute
LN2	Liquid Nitrogen
MBL	Med Biotech Laboratories
Mak	Makerere University
MRC/UVRI & LSHTM	Medical Research Council/Uganda Virus Research Institute & London School of Hygiene and Tropical Medicine
MTA	Material Transfer Agreement
MoH	Ministry of Health
MoU	Memorandum of Understanding

MUST	Mbarara University of Science and Technology
NARO	National Agricultural Research Organisation
NEMA	National Environment Management Authority
NHLDS	National Health Laboratory and Diagnostic Services
OECD	Organization of Economic Cooperation and Development
PPE	Personal Protective Equipment
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RECs	Research Ethics Committees
RNA	Ribonucleic acid
SOPs	Standard Operating Procedures
UNCST	Uganda National Council for Science and Technology
UNHLS	Uganda National Health Laboratory Services

1.0. Introduction

Biological materials and their associated data play a critical role in scientific research contributing to the understanding of certain diseases, advancement of biotechnology and medical research. It encompasses the collection, processing, storage, and distribution of biological samples and their associated data, organized in a systematic approach. A Biobank is defined as a collection of biological material and, the associated data and information stored in an organized system, for a population or a large subset of a population (OECD definition). The biobank collections help in contributing to the efficacy of research as they utilize the full potential of biological samples and their metadata stored in them. These provide platforms for building local capacity and foster international collaborations.

Uganda has seen a move by various institutions setting up biobanks. These guidelines are also applicable to biorepositories, gene banks, biological databases and any other facilities where biological materials and derivatives are stored and preserved for future use. Biobanks shall be: a) established within public or private institutions, and/or international collaborations; b) established using biological samples and/or information obtained from research subjects/communities within the Republic of Uganda; and c) Biological materials imported into the country.

1.1. Rationale

Due to advances in scientific research and health care there is need to formulate appropriate guidance for stakeholders on handling of stored biological materials and their associated data. This especially becomes important due to the need to both advance science and protect the rights and welfare of the donors of the biological materials and associated data. In principle, the rights and well–being of the participants and the common good prevail over the research interests of the custodian organization and end users of the biobank.

1.2. Scope

These guidelines cover the acquisition, storage, processing, sharing and use of biological materials and associated data in; research and technology, health, agriculture; horticulture, animal, forensic, environment, aquatic sciences, wildlife and education. For biological materials/data collected during public health emergencies, surveillance and for quality assurance, these guidelines shall apply. Additionally, these guidelines shall apply to scientific research in all training institutions.

These guidelines give guidance on establishment, governance, management, operation, access, use, biosafety, and accreditation. The biobank should be operated throughout its existence with integrity, transparency and accountability.

Biobanks typically:

a. Collect and store biological materials that are annotated not only with medical, but often also epidemiological data, agricultural, horticulture, animal, forensic, environment, aquatic sciences, wildlife and education;
b. Are not static projects, since biological materials and data are usually collected on a continuous or long-term basis;
c. Are associated with current and/or future research projects at the time of specimen collection;
d. Apply coding or anonymization to guarantee donor privacy but have, under specific conditions provisions that participants remain re-identifiable in order to provide relevant information back to the donors;
e. Include established governance structures and procedures that serve to protect donors' rights, competing priorities and stakeholder interests;
f. Cater for biosafety and biosecurity concerns

1.3. Goal

To establish a coherent regulatory frame work for establishment, operation and accreditation of the biobanks.

1.4. Objectives

1. To ensure that Biobanks are established for custodianship of high quality, highly valuable biological materials and data.
2. To maintain legal requirements and standards in management of Biobanks.
3. To maintain ethical standards in collection, processing, storage or inventory, disposal, use and distribution of biological material and data.
4. To maintain Biosafety and Biosecurity standards in collection, processing, storage or inventory, disposal, use and distribution of biological material.

2.0. Establishment and Certification of Biobanks

2.1 Establishment of biobanks

The establishment of a Biobank shall be initiated by any legally recognized organization which shall act as the custodian on behalf of the donors who are the owners of the biological materials and bio data. The custodian organization shall ensure that a biobank has:

a. Evidence of operation as a legal entity;
b. A clearly defined protocol and scope;
c. Standard Operating Procedures, defining ethical requirements, technical, quality management, information technology, safety and biosecurity requirements;
d. A business plan with evidence of resources in place;
e. A sustainability plan;
f. Governance structure of the biobank;
g. Evidence of proficiently trained and competent personnel;
h. A contingency plan e.g. covering natural disasters and relocation of the biobank;
i. Provision for equitable access by various stakeholders;
j. Certification of the building/infrastructure suitability by Ministry of Works and Urban Planning and Development or the applicable relevant authorities
k. Evidence of Environmental Impact Assessment by the National Environment Management Authority (NEMA);
l. Clearance from the Institutional Biosafety Committee;
m. Have risk assessment plan for the biobank;
n. Have all administrative requirements according to the accreditation committee of the UNCST.

When establishing a biobank, the custodian should carry out consultations with stakeholders, which may include relevant participants, Research Ethics Committees (RECs) and regulatory bodies. The Biobank should explicitly describe and document the nature of the biological materials, their sources and intended purpose for its existence. Biological materials shall include but are not limited to; human and non–human tissues, organs, blood, plasma, sputum, skin, serum, Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), proteins, cells, hair, nail clippings, breast milk, fecal matter, bones, urine and saliva. Other biological specimen may include isolated or cultured microorganisms/pathogens of human origin, vectors of human pathogens, environmental samples, plant and animal products.

2.2. Regulatory Oversight for Biobanks

2.2.1 Roles and Responsibilities of Uganda National Council for Science and Technology (UNCST)

The UNCST is established by the Act of parliament CAP 209 of the Laws of Uganda to develop and implement strategies for integrating Science and Technology (S&T) into the national development process, provide advice to government of Uganda on policy matters necessary for advancing S&T and, oversee and coordinate Research and Development (R&D) in Uganda. Sections 4 and 5 of the UNCST Act (CAP 209) mandates UNCST to "act as a clearinghouse for information on research and experimental development taking place in scientific institutions, centers and other enterprises and on the potential applications.

The Biobanks will be certified by the accreditation committee established by the UNCST to serve the regulatory oversight. This committee will offer independent scientific, and ethical oversight to ensure compliance to laws, ethical, regulatory guidelines, policies and procedures.

2.3. Biobanks governance structure

Every biobank shall have a governance structure in place responsible for management and oversight roles and responsibilities. There should be an established organogram and terms of reference for each position. The governance structure should:

a. Have a diverse composition including but not limited to: scientists, legal personnel, social scientists, ethicists, biosecurity specialists and community representatives
b. Have a biological materials/data access committee that reviews applications, access and retrieval of biological materials and/ or associated data
c. Have self–audit plan to ensure compliance to National and International Standards, laws, regulations, ethical, regulatory guidelines, policies and procedures
d. Have mechanisms to avoid breach of privacy and confidentiality
e. Have reporting mechanisms for compliance in accordance to relevant institutions or regulatory agencies' requirements
f. Have clear definitions of roles and responsibilities and chain of reporting
g. Have the governance and management activities subjected to independent auditing by the specialized committee set up by the UNCST to ensure compliance to laws, ethical, regulatory guidelines, policies and procedures.

2.3.1 Roles of Institutional Biosafety Committee (IBC)

Institutional Biosafety Committees (IBCs) are established by organizations that hold potentially hazardous substances of a physical, chemical and biological (biohazards). Any organization involved in or planning to conduct research with infectious, hazardous, potentially infectious/hazardous substances or material is required to set up or designate a competent IBC. Each IBC formed shall consist of a biosafety officer trained on national bio-risk management curriculum and at least three other officers with appropriate expertise. The IBC shall be certified by UNCST.

Members of the IBC shall ensure the protection of all information and shall protect confidentiality of all information given to them in the course of their work, and shall sign confidentiality agreements with their organizations. In addition, they shall not use information under their consideration for their own research projects or personal gain.

Objectives of the IBC

a. To protect all bio-bank personnel, other users and environment from potential exposure to biological agents.
b. To prevent an intentional release of biological materials from loss, theft and or misuse.
c. To promote occupational health and safety programs in biobank working environments.
d. To comply with all legal requirements applicable to Bio-risk management processes.
e. To enhance monitoring and evaluation of Bio-risk management program.

Functions of IBC

The IBC's function is to minimize potential human and environmental harm that may be associated with research on or with potentially infectious and hazardous substances such as pathogens, radioactive material and applications of biotechnology, especially recombinant DNA techniques and processes.

Specifically, IBCs shall;

a. Conduct biosafety and biosecurity risk assessments before biobank inception;
b. Document all the hazards categorized in the checklist;
c. List the risk groups of the pathogens available based on national/international requirements and advise mitigation methods;
d. Conduct continuous periodic evaluation of the Biobank;
    i. When there is a change in procedures
    ii. When a new biological agent is introduced
    iii. Whenever modification of the biobank infrastructure occurs

e. Advise on the emergency procedures in the event of occurrence of an incident;
f. Conduct biosafety review of research proposals on potentially hazardous substances;
g. Conduct initial and periodic risk assessment of the of the biobank using a structured risk assessment checklist;
h. Conduct periodic biosafety and biosecurity audits of the biobank;
i. Develop relevant biosafety and biosecurity documentations for the biobank;
j. Follow up on the after audits biobank action plans to ensure compliance according to the national and international requirements;
k. Provide guidance or supervise on the operation of pathogen asset control system (such as establishment of an electronic application system used to account or control biological agent stocks).

2.3.2 Roles of the Biobank Custodian

The institution shall appoint a qualified custodian who will ensure compliance of the biobank establishment and management with the relevant policies, procedures and protocols.

a. The Biobank custodian shall ensure compliance with the relevant policies, procedures and protocols. He/she shall ensure that the Biobank protocols and procedures have been subjected to approval by UNCST. Have amendments to the policies and procedures subjected to ethical review and approval.
b. Have in place in liaison with researcher, mechanisms for re-consenting when there are changes that affect the scope of the consent or a consent waiver in circumstances where re-consenting is not possible.
c. The biobank custodian shall have in place mechanisms enabling public access of Biobank related documents, governance, management and oversight documents. This information should include:
    i. Ethical and Regulatory approval records;
    ii. Roles and responsibilities as stipulated in the governance, management and oversight structures;
    iii. Application procedures for access, review and authorizations;
    iv. Summary of the biological materials and associated biodata except where there are biosecurity reasons;
    v. Key elements of the applicable laws, ethical, regulatory guidelines, policies and procedures; and
    vi. Annual reports of compliance to laws, ethical, regulatory guidelines, policies and procedures

d. He/ She shall ensure that stakeholders, including the general community and researchers, are consulted to formulate criteria for prioritizing applications for access to the samples.
e. The custodian is responsible for biobanking communication pertaining to biobank research and developments
f. Ensure information is publicly available on the research projects for which samples and data are accessed, and the results of these projects.

3.0. Sample Acquisition

Prior to obtaining biological materials from sample sources the following should be obtained or in place:

3.1. Community engagement

Reasonable effort to involve community stakeholders before, during and after collection and storage of biological materials shall be made. Community stakeholders may include individuals and groups that are ultimately representing the interests of people whose samples or those of their subjects (animals) are being stored. Engaging with the community is a process of building transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organizations.

The Biobank shall require an appropriate community engagement process before receipt and transfer of biological materials /data. At a minimum community engagement shall include but not limited to documented evidence of; consulting gate keepers of the community; organizing community meetings and involvement of Community Advisory Boards.

3.2. Informed Consent

Documented proof of adequate informed consent for biological material and data donation shall be provided. This shall include; a separate consent document for storage for future use and separate consent document for genetic research where applicable.

3.2.1 Informed Consent Process

All biological materials/data obtained during research, clinical care, public health interventions and surveillance require evidence of documented informed consent from the sample donor or their representative. Each biobank shall have a documentation of the informed consent status for each bio-specimen. Additionally, procedures for obtaining informed consent and protecting the privacy of identifiable human research participants and confidentiality of data and procedures to follow in the case of withdrawal of consent shall be clearly described in relevant biobank SOPs.

During the clinical care process, public health interventions and surveillance the implementer shall document the process of having obtained informed consent from the sample donors. The laboratory request form should have adequate basic information for the participant to decide. The laboratory form should be in triplicate with copies given to the sample donor, laboratory and custodians of the Biobank.

The biobank custodian shall ensure that there are available policies, protocols and procedures in place on the, collection/reception, labeling, registration, processing, storage, tracking, retrieval, dissemination, use, auditing, sharing and certified safe destruction of samples and/or data.

3.3. Administrative Approval for Non-research Biobanking

Evidence of approval of the protocol by respective agencies such as; NHLSD, National Agricultural Organization (NARO) shall be sought prior to archival of the samples to any given non-research biobank.

3.4 Material Transfer Agreement (MTA)

All samples to be stored in the Biobank should be accompanied with an MTA between the custodian institution and the Biobank.

3.5 Data Transfer Agreement (DTA)

Data sharing shall be established between the participating partners with the mutually agreed position documented in a Data Transfer Agreement.

3.6 Manual of Operating Procedures

An operating Manual shall specifically include, but not limited to, Standard Operating Procedures (SOPs) and other documents regarding the following:

a. **Informed consent:** each Biobank shall have a documentation of the informed consent status for each bio-specimen stored in the Biobank.
b. **Equipment monitoring, calibration, maintenance and repair:** each Biobank shall have documented procedures to routinely monitor and maintain equipment that are used for bio-specimen storage or preparation. This includes ensuring that equipment is accurately calibrated, that operational settings are routinely recorded, and that scheduled maintenance and repairs are documented. Equipment SOPs and records shall also cover associated backup and emergency notification systems.
c. **Control of Biospecimen collection supplies (Disposables and Reagents):** a biobank shall have a procedure to ensure that consumable supplies and reagents used for collection, processing, and storage conform to required applicable standards. This includes ensuring purchased supplies are approved, and acquired from approved suppliers, meet defined material specifications, and are in good condition for use.

d. **Bio-specimen Identification and Labelling Conventions:** a biobank shall define policies and procedures for labelling and coding biospecimens and linking or delinking bio-specimens to other data sets and patient informed consent according to national and international standards. However, there should be a documented mechanism for return of useful results.

e. **Bio-specimen collection and processing methods:** a biobank shall establish procedures of bio-specimen collection (including chain of custody), reception, handling, processing, and preservation for each biospecimen type. Biospecimen collection and processing should always include the recording of personnel initials or names, dates, and times to accurately record these potential sources of pre-analytic variation.

f. **Storage and retrieval:** a biobank shall define procedures for the storage and retrieval including processes for adding new bio-specimens, withdrawing bio-specimens, responding to and filling requests, and final disposition of bio-specimens.

g. **Shipping and Receiving:** a biobank shall have defined procedures and policies for the packaging and transport at ambient temperature and frozen bio-specimens to ensure bio-specimen integrity and safety. This includes packaging specifications to maintain appropriate temperature conditions; wet ice, dry ice, and liquid nitrogen (LN2) handling; shipment temperature monitoring; shipment regulations for hazardous materials; shipment logs; delivery notifications; confirmation of delivery; shipment feedback mechanisms; and MTAs or other appropriate agreements to cover transfers.

h. **Laboratory Tests performed in-house including Bio-specimen Quality Control Testing:** each biospecimen resource should have SOPs governing standardized in-house testing procedures and should document the results in associated quality records. This includes tests to assess and control bio-specimen quality, such as confirmation of histopathology diagnosis, nucleic acid integrity, or biomarker expression.

h. **Bio-specimen Data Collection and Management (Informatics):** A biobank should have an up to date inventory database or software that is used to manage its data and information. Each bio-specimen resource should have policies for managing records and procedures defining data access, data collection methods, reporting, data Quality Control (QC), distribution and standardized medical terminology.

j. **Biosafety:** each biospecimen resource should have policies and procedures covering biosafety, including reporting staff injuries, spillage as well as standard precautions for blood borne pathogens, personal protection equipment, hazardous material handling, and disposal of medical waste and other biohazardous materials.

k. **Training:** each bio-specimen resource should have policies and procedures for biobank related training of all staff members and continual education. Such training should be documented.

l. **Security:** security SOPs and policies should include information on points of contact and designated backup personnel, including names and emergency contact numbers. There should be documented policies and procedures to manage corrective actions; to resolve inventory and shipment discrepancies; to monitor all sample storage; access restrictions and to manage power outages, emergencies, and natural disasters.

4.0. Quality Managment

All biological specimen and associated data shall be subject to quality management measures according to national and international standards at every stage of its processing including acquisition, collection, labeling, registration, processing, storage, tracking, retrieval, dissemination, use and destruction in order to ensure high standards of quality in all biobank holdings.

The participant confidentiality shall be assured through quality assurance processes such as; sample tracking and audit trails. The biospecimens shall be maintained through a system that allows all samples, data and any other information to be tracked according to the biobank SOPs. In general, biobanks should implement systems that specify Quality Assurance (QA) for sample collection, processing, storage, shipment, and disposition. Such systems are essential for maintaining a fit-for-purpose biobank.

Biobanks should have appropriate documented QA and QC programs with respect to equipment maintenance and repair, staff training, data management and record-keeping, and adherence to principles of good laboratory practice. All biobank operations must be subject to regular audits. The timing, scope, and outcome of these audits should be documented.

4.1. Biobank standard operating procedures (SOPs)

Biobanks should develop, document, and regularly update policies and procedures in a standardized written format incorporated into an SOP manual that is readily available to all biobank personnel. The SOP manual is a key part of the overall Quality Management System (QMS) of the biobank, is important to the success of biobanking, and is a major contributor to the development of standardized practices worldwide. The SOP manual should specifically include:

a. Procedures for obtaining informed consent and withdrawal of consent from participants;
b. Records management policies, including access control, a backup system, biospecimen annotation, and document maintenance and archiving;
c. Policies and procedures for specimen handling, including supplies, methods, and equipment;
d. Procedures for specimen processing (e.g. collection, transportation, processing, aliquoting, tests, storage, and QC);
e. Procedures for sharing and transferring biospecimens (access policy, MTA); procedures for a business model and cost recovery, where applicable;
f. Policies and procedures for shipping and receiving specimens;

g. QA and QC policies and procedures for supplies, equipment, instruments, reagents, labels, and processes used in sample retrieval and processing;
h. Procedures for security in biobank facilities;
i. Policies and procedures for emergency response to occupational health and safety, including reporting of staff injuries and exposure to potential pathogens;
j. Policies and procedures for the investigation, documentation, and reporting of errors, complaints, and adverse events;
k. Policies, procedures, and schedules for equipment inspection, maintenance, repair, and calibration;
l. Emergency procedures in case of failure of a refrigerator, freezer, or LN2 tank;
m. Procedures for disposal of medical waste and other hazardous waste; and
n. Policies and procedures describing the requirements of recruitment and training programmes for biobank staff.

4.2. Protection of biological specimen and associated data

Processing, handling and storage of biological specimen and associated data shall be conducted in a manner that protects the privacy of the participants and the confidentiality of their biological specimen and associated data. The custodian organization shall ensure that;

a. Data contained within the biobank databases are protected in accordance with applicable domestic laws;

b. A combination of mechanisms such as secure storage of samples and data, coding, Data anonymisation and data pseudonymisation are implemented to ensure privacy and confidentiality;

c. The biobank is established, managed and governed in such a way as to prevent any inappropriate or unauthorized access to or use of participants' biological specimen and associated data'

d. Policies and procedures shall be documented to safeguard the privacy and confidentiality of participants, samples and data, especially those that may allow, directly or indirectly, the identification of the participants;

e. Quality control and assurance measures shall be in place to ensure, security and confidentiality during collection, storage, handling, distribution and destruction of the samples and data;

f. Adequate infrastructure with controlled access to the biobank should be put in place.

4.3. Access to biobank samples and data

The biobank custodian shall ensure that there are available institutional policies, protocols and procedures in place governing access to all biological materials and associated data.

Policies on access shall include but not be limited to the following:

a. Requirements for accessing biological materials and associated data
b. Circumstances under which they provide access to biological specimen and associated data to third parties including restrictions to unlimited access requirements for the return or destruction of biological specimens and data provided to third parties at the completion of their research
c. Prohibitions to sample access for usage as well as physical access should be given by provision of subcategorization of authorization to access of some of the samples within the institution.
d. Institutional Biobank access and fee policies. Transfer, access and use of biological specimen and associated data shall be consistent with the terms of participation and respect the privacy of the participants and their communities' confidentiality of the samples and data, and ensure good safety and laboratory methods.

4.4. Access Control Provisions

a. The biobank custodian shall ensure that access to and use of biological material and data are in line with established protocols that are consistent with informed consent and with respect to privacy and confidentiality.
b. The biobank should provide relevant information about the types of activities and bio-specimens held within the biobank using its resources and whether biological materials and data will be made available to the public for public accountability.
c. The biobank custodians shall ensure that samples and associated data access requests and distribution are consistent with the informed consent provided by the sample donor and the existing data and material transfer policy of the biobank.
d. The biobank should provide to researchers' biological materials and data that are anonymized. However, in exceptional circumstances, it may be in the donor's interest that the researcher has access to non-coded or non-anonymized materials or data with participant's consent. For example, this may be the case for research involving rare diseases.
e. The biobank should have procedures in place by which participants should be directly contacted by researchers, clinicians, public health specialist who have accessed their biological materials and data from the biobank for the returned significant findings.

f. The biobank should not grant access to or disclose participants' biological materials or data to third parties e.g. insurers, Employers, law enforcement agencies or other civil–law agencies, for non–research purposes, except when required by law and surveillance purposes.

g. Biobank material and data access applications shall be reviewed by existing biobank sample access committee to ensure that the proposed uses are scientifically and ethically appropriate and consistent with applicable policies, frameworks and legislation.

h. The biobank should have their access policies readily available for sample donors, communities, clinicians, researchers and third parties to ensure transparency.

1. The biobank should have policies in regard to access to its resources and services ensuring that these are applied in a fair and transparent manner without prohibiting the use of the material and data.

j. Where biological materials and data are to be released to third parties by the biobank, consideration should be given to the implications for the custodianship of any data derived from the analysis of such material that relates directly to participants (e.g. genotype data derived from DNA), particularly where such data can be linked to significant amounts of phenotypic data about the same participant. Such issues should be addressed in the material transfer agreement which governs the release of human biological materials and data from the biobank to the researchers.

k. The biobank should ensure that its governance mechanism is able to deal with problematic situations pertaining to data derived from the analysis of biological materials and other information shared with the third party.

l. The biobank should provide the quantity of materials and data consistent with that required for the research to be carried out. Hence the requesting party must provide information on what they require from the biobank, type of material and quantities.

m. Biobanks should have dedicated storage facilities that are not shared with other activities, for the safety and security of bio specimen collections.

n. Biobanks should be equipped with a system that adequately limits access to authorized staff members and protects against intrusion by unauthorized individuals.

4.5. Records management

Documentation related to sample collection, sample processing, sharing of samples (MTA and DTA), and shipment of samples (proof of shipment and delivery) must be appropriately maintained and archived in a traceable and secure manner.

A backup system must be implemented to guarantee appropriate maintenance of all records. All documentation must be kept centrally and should include: quality certifications; personnel training records; completed templates of forms and spreadsheets; documentation of biobank audits; documentation of adverse events; instrument calibration records; maintenance and repair records; signed informed consents; signed collaboration agreements; sample request forms; signed MTAs and DTAs; and shipping notes.

All hard copies of records must be archived in a secure manner, to be accessed only by authorized personnel. All stored records should be stored in a manner that provides easy access for inspection by authorized personnel. Each container, tank, freezer, refrigerator, or room–temperature storage cabinet should have a unique identifier. The hierarchy of each storage unit should be clearly defined, to enable stored samples to be located easily. A convention should be established for numbering shelves, racks, and boxes as well as each location within the container. An IT solution can provide a centralized system to maintain traceable records of samples. Where possible, hard copies of records should be scanned into an IT system to provide a backup.

All records should be archived for a period in line with local regulations. Records pertaining to samples that no longer exist may be destroyed if the records are considered to no longer be valuable. Records pertaining to samples that were withdrawn should be destroyed in a secure manner. In addition, Records pertaining to instruments may be destroyed once the instrument has been retired. The destruction of records should be carried out in a manner in line with the security requirements of the record.

5.0. Specimen Transportation and Shipment

The transportation and shipping of biospecimens shall be conducted according to international standards and national guidelines in line with the mode of transport to be used as well as type of sample.

6.0 Biosafety and Biosecurity

The primary, basic requirement of a biobank is general safety. This includes protection of people and of the environment against biological and chemical hazards. The management of these risks should be based on a general implementation of a precautionary principle similar to those used in laboratories and clinical setting and should be embodied in a general safety management plan.

6.1. Biosafety

Biobanks must follow established national and international standards and guidelines in relation to chemical, physical, and biological hazards.

The use of liquid gases such as LN2 for cryopreservation poses a serious source of hazard. Where LN2 refrigeration is used, an adequate supply of refrigerant must be maintained. The supply maintained on–site should be at least 20% more than the normal refill use, to allow for emergency situations. Handling LN2 has serious safety implications. Skin contact with LN2 can cause severe frostbite. Oxygen–level sensors should always be used when LN2 containers are used in a biobank. LN2 expands to 650 times its original volume at room temperature, causing a form of explosion hazard if evaporation is restricted. Storage areas must be well ventilated. Plastic and glass containers can easily explode if liquid is trapped when the container is removed from the LN2. Protective safety equipment must be worn when handling LN2.

Appropriate Personal Protective Equipment (PPE) based on risk assessment that should be used such as cryogenic gloves, a face shield, mask and a protective garment should always be worn. Protective shoes are also recommended. Safety notices and protocols must be clearly displayed in the biobank area.

Work in a biobank also entails several occupational hazards typical of the laboratory environment. Appropriate training on safety, including LN2 safe handling and means of protection, must be given to personnel before they work in a biobank, and should be repeated on a regular basis.

In addition, electrical safety is an important concern. Freezers must be properly wired to adequate sources of electrical supply, and grounded. These risks must be taken into account before setting up a biobank, and their prevention must be integrated into all aspects of the SOPs of the biobank.

6.2. Biosecurity

Laboratory biosecurity describes the protection, control, and accountability for valuable biological materials, to prevent their unauthorized access, loss, misuse, theft, or intentional release. The scope of laboratory biosecurity is broadened by addressing the safekeeping of all valuable biological materials, including not only pathogens and toxins but also scientifically, historically, and economically important biological materials, such as collections and reference strains, vaccines and other pharmaceutical products, food products, genetically modified organisms, non-pathogenic microorganisms, extraterrestrial samples, cellular components, and genetic elements.

Biosecurity can also refer to precautions that should be taken to prevent the use of pathogens or toxins for bioterrorism or biological warfare. Securing pathogens and toxins at research and diagnostic laboratories cannot prevent bioterrorism but can make it more difficult for potential terrorists to divert material from a legitimate facility to build a biological weapon. Nothing in the foregoing constitutes a ban on dual use of biological specimens.

Laboratory biosecurity measures should be based on a comprehensive programme of accountability for valuable biological material that includes:

a. Assessment of biosecurity risks;
b. Restricted and controlled access;
c. Containment-in-containment architecture;
d. Regularly updated inventories with storage locations;
e. Identification and selection of personnel with access;
f. Plan of use of valuable biological material;
g. Clearance and approval processes; and
h. Documentation of internal and external transfers within and between facilities and of any inactivation and/or disposal of the material.

Institutional laboratory biosecurity protocols should include how to handle breaches in laboratory biosecurity, including:

a. Incident notification;
b. Reporting protocols;
c. Investigation reports; and
d. Recommendations and remedies.

Adoption of these security requirements is important for biobanks that store pathogenic or toxic bio-specimens.

6.3. Facility and Infrastructure

The biobank infrastructure and storage system depend on the type of material being stored, the required storage conditions, the anticipated period of storage, the intended use of the materials, and the resources available for purchasing the storage equipment. The storage infrastructure also depends on the available resources and support to the biobank. The data and databases related to bio-specimen annotation, quality, storage location, and use, are important attributes of biobank infrastructure.

The storage system is fundamental to maintaining high sample quality and to meet international standards freezers, power back and other equipment need to be in place and maintained.

7.0 Qualification, Education and Training

The Biobank shall ensure that all personnel are competent with knowledge and skills to run a Biobank. The Human resource in the Biobank shall be qualified by training and experience to carry out its mandate.

a. The biobank custodian should be knowledgeable in biological laboratory sciences.
b. The biobank custodian shall ensure that personnel have the appropriate professional qualifications that meet recognized standards, underpinned by experience, skills, up-to-date knowledge, education and training and are assigned responsibilities commensurate with their capabilities.
c. The biobank custodian shall develop and implement periodic employee training programs. Training should form an integral part of the biobank certification system. Technical staff of the biobank shall be responsible for the implementation of policies and procedures
d. GLP shall be required of the personnel working in a health-related biobank every two years.

8.0 Ownership and Custodianship, Benefit Sharing and Intellectual Property

8.1 Ownership and Custodianship

Sample donors own the samples which are kept in trust by the primary source institution (where the sample is collected and/ or where the primary interaction with the donor takes place in a duly registered and recognized organization in Uganda.). Whether to link or de-link samples will be determined by the sample donors during the informed consent process which shall be appropriately documented. Samples donors may withdraw their samples if the samples are linked. The primary source institution shall have the authority to decide use, transfer, storage and future use of the samples taking into consideration rights and welfare of the sample donor. The biobank has full custody of the specimen as per the MTA drawn between the parties.

8.2 Intellectual Property

Intellectual Property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. These include; markers for developing assays and guides for identifying new potential targets for drugs, therapeutics, and diagnostics. Intellectual Property rights grant the owner of the work exclusive rights to exploit and benefit from his/her creation.

Patenting of technology suitable for subsequent private investment should lead to the development of products that address public needs without impeding research or the rights and welfare of the sample donors and communities.

The biobank and primary source institution should define an intellectual property policy and relevant aspects of this policy should be defined in the MTA and/or DTA. The primary source institution shall ensure the following;

a. The primary source institution shall ensure there are available policies and procedures on benefit sharing in line with applicable national policies, regulations and laws;
b. Benefits from IP are shared in different ways and should be pre-negotiated these include the; financial benefits, information, licensing, or transferring of technology or materials;
c. The derivatives from the donors' biological material shall be taken as new products and should be considered as Intellectual Property;
d. The biobank shall require that they are acknowledged in publications and presentations;
e. Sample donor institutions and communities' acknowledgement in publications, presentations.

9.0. Discontinuation of the Biobank and Disposal of Materials and Data.

9.1. Discontinuation of a biobank

The operators of the biobank should plan for its possible discontinuation and should have a suitably detailed policy setting out the manner donor biological materials and data that it holds will be dealt with in the event of its discontinuation.

Where a biobank of scientific value can no longer be supported by its current operators, efforts should be made to transfer the biological materials and data to another biobank or another entity. Once a biobank is no longer required or is no longer of scientific value and it has been determined that it will be discontinued, the biological materials should be disposed of in an appropriate manner, consistent with the principles of consent, privacy and confidentiality.

The biobank's discontinuation plan should include details for the transfer or destruction of the biological materials and data. Where the discontinuation of the biobank results from insolvency, the operators should be aware that under applicable insolvency law the liquidator may be permitted or required to sell the assets of the biobank to commercial buyers, subject to any constraints in the participants' consent or under the law. All assets from a biobank shall be thoroughly disinfected and documentation of this shall be provided to the IBC. The operators should consider what steps should be taken to provide for this and make information available to participants.

For the human biological biobanks, one shall only sell movable assets and not the samples under custody. The biobank's guidance on the destruction and disposal of biological materials and data should take into consideration cultural heritage and/ or religious beliefs known or disclosed by the participants, and/or their communities.

The operators of the biobank should ensure that all information and data it holds is destroyed in a manner not permitting its recovery in accordance with the state of the art and technology. The operators of the biobank should dispose of biological materials in accordance with national and international legislation and regulation applicable to the disposal of biological materials and bio-hazardous waste. Transportation to disposal facilities should be secure to avoid any leakage of samples and or data.

A biobank should monitor specimen quality as part of its Quality Management (QM) and destroy those samples that are compromised. All destruction procedures should be documented.

Samples/Biospecimen and /or data transferred to third parties or a new custodian should be documented. The terms, conditions and agreements under which biospecimens and/or data were obtained should be consistent and maintained and copies of records should be archived at both facilities (new custodian and old custodian). Before a Biobank is terminated the following shall be done:

a. One-year notice to all stakeholders is provided;
b. SOPs for the safe transfer of the samples are in place;
c. Documented justification for closure is available;
d. Audit report by the IBC is submitted to the NBC
e. Approval of termination by the UNCST

9.2. Disposal of materials and data

The procedure for disposal of biological materials and data shall be explained in the relevant SOP. A certificate of destruction of samples in a biobank shall be provided by a competent agency approved by the NBC. For samples sent of outside Uganda in collaborative engagements, the certificate of destruction must be provided by the recipient institution through the provider institution.

10.0. Disaster Preparedness and Recovery Planning for Biobanks

Biobanks should have a written disaster recovery plan in place for responding to a wide variety of emergency situations for business continuity. The plan should cover a wide range of natural and man-made disasters, which must be categorized with their various effects on the biobanks' ability to carry out its essential functions. Assessment of likelihood of various types of disasters e.g. chemical spills, fire, floods, power outage should be documented within the plan.

The recovery plan should be tested at least annually to ensure that it fulfills the purpose. A notification report of this shall be documented and submitted to the IBC.

10.1. Biological material protection and recovery

Biobanks have a fundamental objective to protect every single specimen and whole collections in its custody to minimize hazards such as; spillage, contamination, floods, staff exposure while maintaining the sample integrity.

a. Biobanks should have a backup that is adequate for disaster handling and management. For example, backup freezers, power backup and data servers.
b. Duplication of specimen collections and data in distinct locations (e.g., including

in different freezer units) is recommended to ensure preservation of the holding in the event of a catastrophic event.

c. The biobank should be placed on a list of "high priority" users for power restoration following an emergency and this shall be documented.

d. Notification of security and environmental monitoring systems should be verified on a routine basis and documented. Where possible, emergencies should be simulated to ensure proper follow-through for the established emergency plan.

10.2. Data Protection and Recovery

a. The biobank sample inventory should be backed by an off site server;

b. If biobank sample inventory is not housed on a local server, some consideration should be given to storing electronic inventory records on site to ensure that needed records are accessible in an emergency.

10.3 Biobank Personnel

a. All biobank personnel should be trained and knowledgeable on the procedures laid out in the recovery plan.

b. The biobank should have a checklist of activities for "on call" staff to follow during an emergency. "On call" staff should be familiar with the location and operation of certain key equipment and controls (i.e., circuit boards) that may need to be checked during an emergency.

c. Emergency telephone numbers for professional assistance should be clearly posted in the biobank and accompanying administrative areas e.g., engineering or facilities personnel, power companies, fuel supply companies, transportation services.

d. SOPs of emergency plans should be available at the biobank for the relevant potential disasters identified. This should include components on preparedness, response and recovery.

11.0. Collaborative Engagements

The collaborative framework should be drawn at protocol development and before collection of the biological materials. This shall be in a clearly written Memorandum of Understanding (MoU). Collaborators are required to build, develop or strengthen local capacity for any investigative testing. Collaborating institutions partners shall agree on appropriate data storage, access and use rights.

11.1. Responsibilities of Stakeholders

11.1.1 Role of the Sample Donor

The sample donor is responsible for the following;

a. understanding and updating the Informed Consent
b. Provision of donor materials

11.1.2 Role of the Research, Healthcare and Public Institutions

a. Effective community engagement to increase public awareness and acceptability of biobank activities;
b. Appropriate documentation e.g MTAs, MoUs, ICFs, SOPs and regulatory approvals
c. Appropriate handling and safety of biological materials
d. Maintaining privacy and confidentiality of sample donors;
e. Obtaining informed consent from sample donors;
f. Dissemination of results for maximum impact;
g. Translation of results to action and policy;
h. Capacity building of research and public institutions through technical and infrastructural developments;
I. Custodianship of samples
j. Ensure sustainability of the Biobank

11.1.3 Role of the Researchers

The researcher is responsible for the overall conduct and supervision of the research project in collaboration with the biobank custodian. Specifically, the researcher shall:

a. Demonstrate ownership (e.g. by signing the protocol) of the research protocol and ensure that the protocol is strictly followed at project implementation.
b. Not implement changes/amendments in the research protocol without prior approval of the REC/IACUC/NBC, except when necessary to eliminate an apparent immediate hazard or danger to research participants and their communities.

c. Obtain adequate informed consent from research participants in accordance with the National Guidelines for Research Involving Humans as Research Participants and National Guidelines for Research Involving Animals as Research Subjects.
d. Inform the biobank, REC/IACUC/NBC and the national authorities about early termination of the study, reasons for the termination and their effect on the biological materials in the biobank;
e. Ensure proper documentation of all study records, procedures in collection, processing and transportation of biological samples to the biobank;
f. Put in place a quality assurance system for proper conduct of the study in order to preserve integrity of the biological samples and associated data;
g. Ensure appropriate and timely feedback to the sample donor of the research process and findings.
h. Effective community engagement should be carried out by the researcher before recruitment of specimen donors and continuously thereafter.
i. Have adequate time to implement/ supervise the collection, processing, transportation and storage activities of the biological samples.
j. Take, together with his/her research team, a recognized research ethics course and GCP/GCLP and other relevant training within two years prior to commencement of the study; and thereafter, have a refresher course at least once every two years.
k. Be sufficiently qualified and competent to carry out the research project, and shall, where necessary, have the appropriate professional license to practice.

12.0 Sanctions

Non-compliance with these guidelines may lead to:

a. Revocation of research approval for a study found to be non-compliant;
b. Withdrawing research biobank registration permits of researchers involved in repeated non-compliance;
c. Suspension and eventual termination of ongoing studies at the site or organization;
d. Withholding approval of new studies to be conducted at the organization;
e. Disciplinary action by relevant professional bodies for cases of suspected negligence and malpractice;

13.0 Appeal

The biobank authorizing personnel who is dissatisfied with the accreditation committee's and/or the IBC's decision may appeal to UNCST's management within 30 calendar days after receiving the communication. UNCST shall then carry out an independent review to obtain an objective stand.

14.0 Glossary

TERM	DESCRIPTION
Anonymization	Involves completely removing all identifying information from specimens and data, eliminating the possibility of re-identifing the participants or recontacting donors.
Biological Materials	Any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.
Biobank	A collection of biological material and, the associated data and information stored in an organized system, for a population or a large subset of a population. (OECD definition).
Bio-data base	biological specimen associated data, and related information which include information collected in the establishment of the database and information that is obtained through routine patient care or research on the material held (e.g. personal, clinical, genetic, biochemical or phenotypic information).
Biosafety	Technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release
Biosecurity	are measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins
Bio-risk Management	A combinations of biosafety and biosecurity practices.
Biodata	The biodata includes relevant factual information about an sample donor, such as: date of birth, gender, religion, height, complexion, father's name, geographical location etc
Biological databases	This a collection of data on a given specimen that is organized so that its contents can easily be accessed, managed, and updated. They contain information gene function, structure, localization (both cellular and chromosomal), clinical effects of mutations as well as similarities of biological sequences and structures.

TERM	DESCRIPTION
Biological material donation	This is material that includes and is not limited to; blood, sputum, saliva, hair, fecal matter, skin that is provided by a sample donor to the researcher or biobank custodian
Communities	This is the environment from which the sample donor is obtained. This includes the persons living with and around the sample donor
Derivatives	This is a new, original product that includes aspects of a preexisting, already copyrighted work
Disaster	This is a serious disruption occurring over a relatively short period of time, affecting the functioning of a community or a society as it causes widespread human, material, economic or environmental loss which exceeds the ability of the affected community or society to cope using its own resources
Gene Bank	This is a type of biorepository which preserve genetic material. For plants, this could be by in vitro storage, freezing cuttings from the plant, or stocking the seeds (e.g. in a seedbank). For animals, this is the freezing of sperm and eggs in zoological freezers until further need
Hazard	This is a something that is dangerous and likely to cause damage.
Publicly available	This is information that has been published or broadcast for public consumption, is available on request to the public, is accessible on-line or otherwise to the public, is available to the public by subscription or purchase, could be seen or heard by any casual observer,
Pseudonymisation	This is a data management and de-identification procedure by which personally identifiable information fields within a data record are replaced by one or more artificial identifiers, or pseudonyms
Sample donor	This refers to individuals or their representatives from whom consent is obtained for use of research samples.

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Annexes

ANNEX I: Biobank Certification Checklist and Response Document

SECTION A

A.1 Details of Biobank

Biobank institution of affiliation		
Administrative head of the institution		
Contact details of institution	Telephone:	Email:
Biobank physical Address		
Biobank Name		
Name of Biobank Custodian		
Custodian contact details of institution	Telephone:	Email:

A.2 Details on Assessors

Name of assessors	
1.	
2.	
3.	
4.	
Date of assessment	
Date of report submission	

A.3 Biobank personnel in Attendance

Name	Position/ role
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	

SECTION B

Findings from the assessment will be categorized as Critical, Major, Minor or others. Response to all findings will be required in the format of a CAPA Corrective Action Preventative Action plan (attached). A summary of all findings will be entered into a plan and submitted to the Biobank custodian. The CAPA must be returned to the National certification committee within twenty (20) working days of issue. This requires the Biobank custodian and National certification committee contact to explain what action they will take, not necessarily take the action at that point in time.

Critical shortfall	A shortfall which poses a significant risk to human safety and/ or dignity or is in breach of the National Research Guidelines for Biobanking or associated directions Or – A contribution of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.
Major shortfall	A non–critical shortfall that poses a risk to human safety and/or dignity, or indicates a failure to carry out satisfactory procedures, or indicates a breach of the relevant codes of practice, the National Research Guidelines for Biobanking and other professional and statutory guidelines, or has the potential to become a critical shortfall unless addressed Or – A combination of a number of minor shortfalls, none of which is major in its own right, but which together could constitute a major shortfall and should be explained and reported as such.
Minor shortfall	A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards/good practice.
Others	Where a shortfall has not been identified, but areas for improvement have been identified, leading to the assessor providing advice to the biobank custodian on improvements.

B.1 Type of assessment

Type	Tick (where appropriate)
New application	
Re-submission	
Renewal	

B.2 Decision from assessment

Decision	Tick (where appropriate)
Recommended for certification as is	
Recommended for certification subject to minor revisions	
Recommended for re-assessment	
Rejected	

B.3 Are there any outstanding issues from the last assessment? Yes …. No …… If yes, please fill out section below. If no, please go to part 1 of the assessment form.

Outstanding actions from last assessment

SECTION C

Part 1: Checklist for document review

Please ensure that the documents listed below are available on the day of the assessment

Manual of operating procedures for the following		Yes	No	N/A	Comments
1.1	Quality manual				
1.2	Equipment monitoring, calibration, maintenance and repair SOP				
1.3	Control of Biospecimen collection supplies SOP (Disposables and Reagents)				
1.4	Biospecimen identification and labelling Conventions SOP				
1.5	Verification of Informed Consent procedures				
1.6	Biospecimen collection and processing methods SOP				
1.7	Storage and retrieval SOP				
1.8	Shipping and Receiving SOP				
1.9	Laboratory Tests performed in-house including Biospecimen Quality Control Testing SOP				
1.10	Records and document control SOP				
1.11	Bio-specimen/ Data Collection and Management (Informatics) SOP				
1.12	Biosafety SOP				
1.13	Training SOP				
1.14	Security SOP				
1.15	Business plan				
1.16	Collaborative framework for sharing of bio specimen/data SOP				
1.17	Destruction of bio specimen and data SOP				
1.18	Privacy and confidentiality SOP				
1.19	Contingency plan				

Part 2: Biological material management systems.

Identify if samples are legible, collection date, consent is in place and storage location matches records.

No.	Sample ID number	Are details legible on samples? (Y/N)	Does storage location match database/ sample log? (Y/N)	Appropriateness of biological material storage for end use (Y/N)	Non-conformance details
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Part 3: Data Management systems

Identify if samples are legible, collection date, consent is in place and storage location matches records.

No.	REC/Study Number (Where applicable)	Proof of consent (Y/N)	Data access/ restrictions in place (Y/N)	Data backup mechanisms in place (Y/N)	Data sharing log available? (Y/N)	Non-conformance details
1						
2						
3						
4						
5						
6						
7						

8						
9						
10						

Part 4: Administrative issues

Function responsibilities and duties		Yes	No	N/A	Comments
4.1	Human resource manual				
4.2	Documented Biobank organogram (s)? Is this kept current?				
4.3	Do you have a current floor plan?				
4.4	Environmental Impact assessment report approved by NEMA				
4.5	Legal entity of the Biobank				
4.6	Institutional Intellectual Property Policy				

Part 5: Suitability of premises, facilities and equipment.

The premises are fit for purpose		Yes	No	N/A	Comments
5.1	Risk assessment report approved by the Institutional Biosafety committee (IBC)				
5.2	Policies in place to review and maintain the safety of staff and authorize visitors and students.				
5.3	Policies are in place to ensure that the premises are secure and confidentiality is maintained (locked access to tissues/samples)				
Environmental controls are in place to avoid potential contamination					
5.4	Documented cleaning and decontamination procedures (SOP). Staff given training relating to housekeeping				

There are appropriate facilities for the storage of human biological materials, consumables and records					
5.5	Relevant material and records are stored in suitable secure environments and precautions are taken to minimize risk of damage, theft or contamination.				
5.6	Contingency plans are in place in case of failure in storage area.				
5.7	Critical storage conditions are monitored and recorded. e.g. freezers and −80				
5.8	Is there a documented process to deal with emergencies on 24−hour basis. What to do in an emergency of storage failure in the facility and contact list for each area.				
5.9	What system do you use to monitor freezers/−80/ fridges?				

5.10	Do you have records indicating where the relevant material is stored in the premises and are these kept up to date and reviewed? Which use a system do you use to track the samples e.g. Freezer works				
Systems are in place to protect the quality and integrity of human biological materials during transport and delivery to a destination					
5.11	Documented policies and procedures for the appropriate transport of relevant material				
5.12	A system is in place to ensure that traceability of relevant material is maintained during transport.				
5.13	Is there a documented process and a set of master forms to be used for transportation and delivery;				
5.14	Are there any records of Material Transfer Agreements of relevant material.				
Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored					
5.15	Records of calibration, validation and maintenance, including any agreements with maintenance companies.				

5.16	Training records on the relevant equipment?				

Part 6: Governance and Quality systems standards

All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process		Yes	No	N/A	Comments
6.2	Regular governance meetings are held; for example, health and safety and risk management committees which have agendas and minutes.				
6.3	There are procedures for all activities that ensure integrity of specimen/ data and minimize the risk of contamination.				
There is a documented system of quality management and audit					
6.3	Schedule of biobank internal audits and internal audit reports				
Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		Yes	No	N/A	Comments

6.4	Qualifications of staff and training are recorded, records showing attendance at training e.g. CV, experience evidence, training courses attended….				
6.5	Orientation and induction programs. (New starter)				
There is a systematic and planned approach to the management of records		Yes	No	N/A	Comments
6.6	Documented procedures for the creation, amendment, retention and destruction of records.				
6.7	Regular audit of record content to check for completeness, legibility and accuracy.				
6.8	Back-up / recovery facility in the event of loss of records on IT systems.				
There are documented procedures for distribution of human biological materials		Yes	No	N/A	Comments
6.9	A process is in place to review the release of relevant material to other organizations.				
6.10	MTA awareness – An agreement is in place between the establishment and the organization to which relevant material is supplied regarding the tracking and use of material and eventual disposal or return. e.g. open specimen etc..				

A coding and records system facilitate traceability of human biological materials, ensuring a robust audit trail		Yes	No	N/A	Comments
6.11	There is an identification system which assigns a unique code to each donation and to each of the products associated with it.				
6.12	Do staff understand consent and have consent training?				
6.13	An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom.				
There are systems to ensure that all adverse events are investigated promptly					
6.14	Corrective and preventive actions are taken where necessary and improvements in practice are made e.g. CAPA, continuous improvement plan.				

Part 7: Consent standards

Consent is obtained in accordance with the requirements of the National Research Guidelines for Biobanking and as set out in the code of practice (where applicable)		Yes	No	N/A	Comments
7.1	Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose				
7.2	Consent procedures have been ethically approved.				

7.3	Agreements with other Trusts and Third Parties for appropriate consent				

Part 8: Disposal standards

There is a clear policy for disposing of human biological materials		Yes	No	N/A	Comments
8.1	Training log on the disposal SOP				
8.2	Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal				
8.3	There are agreements with disposal contractors				

Report written by:

Printed name:
Signature:
Date:

CAPA Report – Biobank assessment Response Document

Audit Date: CAPA report date: Date response required:

No	Category	Finding	Immediate/ Corrective Action	Preventative Action	Completed by – Initials & Date Completed

CAPA report to be completed by:

Biobank custodian name:
Mobile number:
E-mail:
Signature:

Completed CAPA report to be approved by:

Designated Individual:
Signature:
Date Audit Closed:

ANNEX II: IBC Risk Assessment Checklist for Biobanks

SECTION A.

Details of Biobank

Biobank institution of affiliation		
Administrative head of the institution		
Contact details of institution	Telephone:	Email:
Biobank physical Address		District:
Biobank Name		
Name of Biobank Custodian		
Custodian contact details of institution	Telephone:	Email:

Details of inspectors from the IBC

Name of assessors	Designation
1.	
2.	
3.	
4.	
5.	
Date of assessment	
Date of report submission	

Audit Scoring Criteria

1. For each of the sections listed below, responses to all questions must be, "Yes," or "No," or "Partial" (where applicable).

2. Indicate "Yes" only when all elements are satisfactorily present. Evidence of compliance should be present in a tangible and/or observable form, e.g., written material, physical items, etc.

3. If the site has a written procedure but no evidence is found of consistent implementation or if there is evidence of non-adherence, then the element should be scored as "Partial."

4. If the element (e.g., SOP or job aides) requires a written procedure but it is not available at the site, then the element should be scored as "No."

5. When marking "Partial" or "No," provide comments for each "Partial" or "No" response.

SECTION B

Does the biobank store or plan to store any of the following?

Recombinant or Synthetic Nucleic Acids	Yes ☐ No ☐
Select Agents	Yes ☐ No ☐
Research animals	Yes ☐ No ☐
Chemical Hazards	Yes ☐ No ☐
Radiation Hazards	Yes ☐ No ☐
Dual Use Research of Concern (DURC)	Yes ☐ No ☐
Human Blood and Body Fluids	Yes ☐ No ☐
Use of High Containment Laboratories (BSL3 [E] and BSL4)	Yes ☐ No ☐
Import/Export or transfer of Infectious Material	Yes ☐ No ☐
Microorganisms	Yes ☐ No ☐

(If yes, please give details below)

Genus and Species	Strains

SECTION C

Parameters to Assess	Scoring criteria				Comments
A. Biological Materials	Y	P	N	N/A	
Is the biobank in possession of Tier 1 select agents and toxins?					
If toxin list:					
Name:					
LD50:					
Source organism:					
If select agent list:					
Name:					
LD50:					
Source organism:					
Is there material cell Culture? If yes:					
Name:					
Origin:					
Are there biological specimens?					
If yes, name specimen matrix (e.g. blood, sputum) ……..					
Are there environmental specimens?					
If yes, name sample matrix (e.g. soil, water) ……					
Is the material received from outside source?					
What is the district/country of origin of the material? ……					
B. Documentations	Y	P	N	N/A	Comments

Parameters to Assess	Scoring criteria				Comments
Are there relevant guidelines, SOPs, related to biobank available? (Check applicable standard for required documents)					
As per the license, Is there documentation for: inactivation of live biological agents?					
attenuation of biological agents?					
Handling of live biological agents?					
Does the biobank have inventory management policy of select biological agents?					
Does the biobank have a policy on the transfer of biological materials?					
Does the biobank maintain and update inventory records?					
Does the inventory system in the biobank include detailed information regarding the location of the biological agents					
Are there biohazard signage at the entrance of Biobanks and storage spaces to indicate presence of biological agents without revealing the organisms?					
C. Risk Evaluations	Y	P	N	N/A	
For each of the identified biological materials; What is the infectious Dose of the biological materials? ……					

Parameters to Assess	Scoring criteria				Comments
What is the Case Fatality Rate? ……..					
What is the incubation period? ……					
Is the biological agent airborne?					
Is the biological agent zoonotic?					
Is the biological agent Vector borne?					
What is the Stability of the agent in the environment? ……..					
Routes of transmission (check all that apply):					
Inhalation					
mucosal membrane exposure					
Ingestion					
percutaneous (e.g. animal/insect bite/needle stick)					
Check additional information: (e.g., History of (Laboratory Acquired Infection), symptoms/severity of infection)					
Does the biological material generate Aerosol?					

Parameters to Assess	Scoring criteria				Comments
Do material procedures involve use of equipment below? (check all that apply):					
Centrifuge/micro-centrifuge					
Sonicator					
Aerosolization chamber					
Homogenizer					
Shaker					
Vacuum/aspirating equipment					
Cell sorters					
Pipettes					
Sharps (e.g. needles, scalpels)					
Grinding equipment					
Vortex					
Other _____					
Does it require disinfection before transfer?					

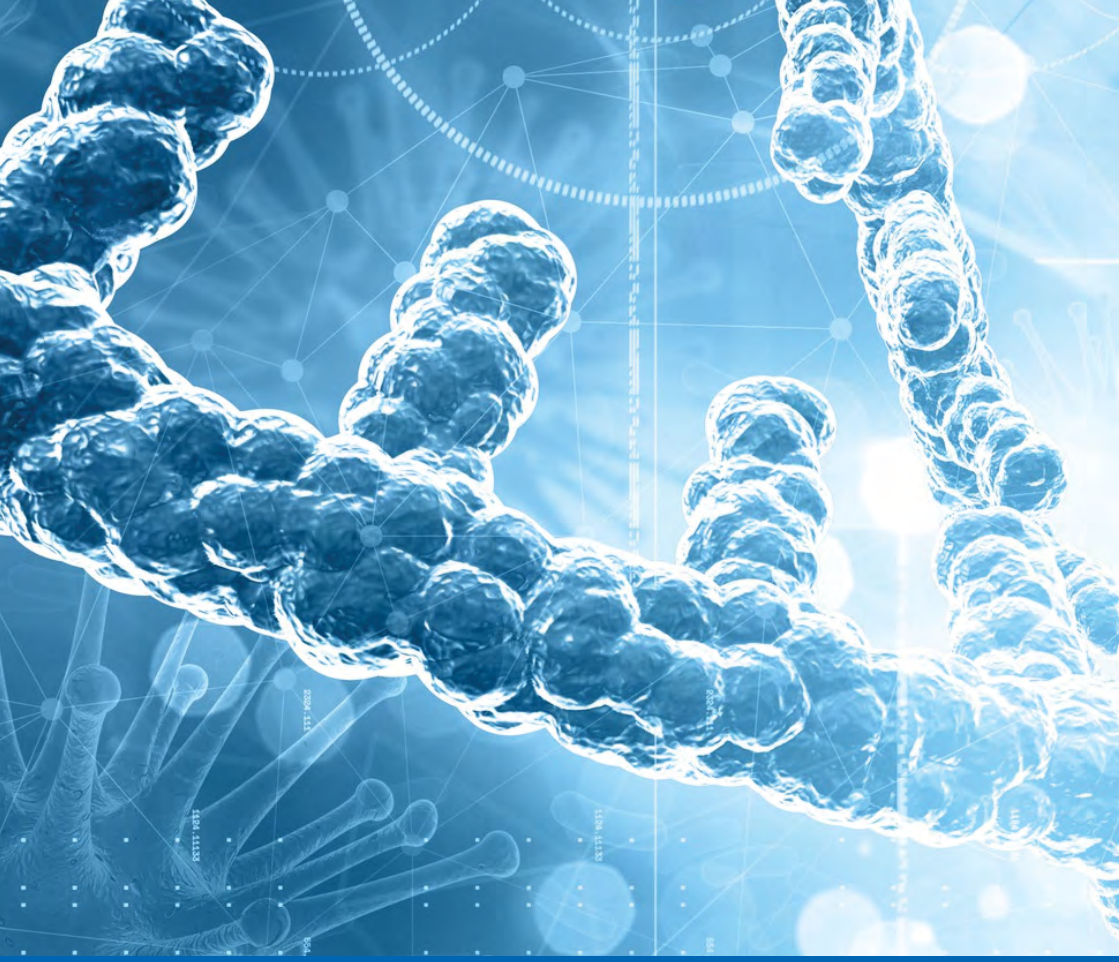
Parameters to Assess	Scoring criteria				Comments
What is the Severity of the biological agent? (Negligible, Minor, Serious, Critical or Catastrophic (Virulence versus severity and pathogenicity) ……					
What is the probability of infection? (Improbable, Remote, Occasional, Probable, Frequent ……					
What quantity is being stored? (Large Scale 10 L or greater) ……					
D. Occupational Health	Y	P	N	N/A	
Is there local/onsite availability of effective prophylaxis? If yes, specify……					
Is there local /onsite availability of effective Post Exposure prophylaxis? If yes, specify……					
Are first-aid boxes provided at strategic locations?					
Are the premises maintained in a clean and orderly way?					

Parameters to Assess	Scoring criteria				Comments
Is medical evaluation performed for workers who may be exposed to pathogens at time of employment?					
Is medical evaluation performed for workers post-employment?					
Does the institution have a health policy including a provision for vaccination in place?					
If yes, is the policy based on a risk assessment of the hazards workers, contractors, and visitors that maybe exposed?					
E. Personnel Training	Y	P	Y	N/A	Comments
Is there a list of all trainings biobank staff received prior to working with agent(s)/material(s)?					
Is there a list of continuous refresher trainings?					
Do the trainings include specifics of: a) Equipment use					
b) Procedures performed					
c) Required biosafety, biosecurity and other safety practices?					
d) Shipments of infectious substances?					
e)GCLP training					
f) Others , specify					
F. Equipment (Primary barriers)	Y	P	Y	N/A	Comments

Parameters to Assess	Scoring criteria				Comments
Are relevant equipment for biobank available?					
Are the required Engineering/ mechanical controls (Primary barriers) in place; Biological Safety Cabinet (BSC)					
Ventilated animal cage					
Chemical fume hood					
rack system					
Glove box					
Sealed centrifuge rotors					
Safety centrifuge cups					
Other(s)…….					
Are all equipment certified and safe for use?					
Are procedures available for decontaminating equipment prior to maintenance?					
Are equipment maintenance records available?					
Are the available equipment maintenance records up to date?					
G. Facility (Secondary barriers)	Y	P	N	N/A	Comments
Is there access control restriction?					
Does the management enforce an access control policy?					

Parameters to Assess	Scoring criteria				Comments
Is the biobank located in an area with minimum traffic from unauthorized personnel?					
Is there availability of a hands free hand-washing sink? Is there availability of safety showers available?					
Is there availability of an eye washing station					
H. Personal Protective Equipment (PPE):	Y	P	N	N/A	Comments
Are there appropriate PPEs available for use in the biobank? Please					
Are the follow PPEs available? (Tick all that apply): Lab coats and aprons					
Latex Gloves					
Safety glasses or goggles					
N-95 respirator					
For select agent handling					
Others, specify……					
I Emergency response	Y	P	N	N/A	Comments
Does the biobank have an emergency response plan to effectively respond and control biological emergencies?					
If yes, does the plan cover: Management of biological spills?					
Management of chemical spills?					
Emergency drills or exercises?					

Overall Project Risk: Low (minimal) ☐ Moderate ☐ High ☐



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